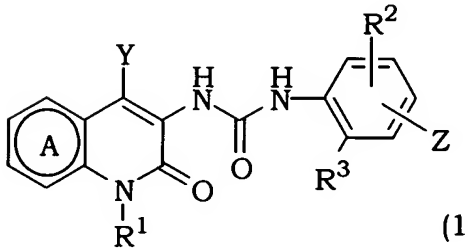
AMENDMENTS TO THE CLAIMS

1. (Original) An agent for treating hyperlipidemia or arteriosclerosis comprising

(A) 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor or a prodrug thereof or a pharmaceutically acceptable salt of the same and/or ezetimibe or a prodrug thereof or a pharmaceutically acceptable salt of the same; and

(B) a compound of the formula (1):



(1)

wherein Ring A is a substituted or unsubstituted pyridine ring;

Y is a substituted or unsubstituted alkyl group, a substituted or unsubstituted cycloalkyl group, or a substituted or unsubstituted aromatic group;

R^1 is a hydrogen atom, a substituted or unsubstituted alkyl group, a substituted or unsubstituted alkenyl group, a substituted or unsubstituted alkynyl group, or a substituted or unsubstituted cycloalkyl group;

R^2 is a hydrogen atom or a lower alkyl group;

R^3 is a lower alkyl group;

Z is a group represented by either of the following formula 1) or 2):

1)

$—D^1—Q$

wherein D^1 is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, Q is a hydroxy group, a carboxyl group, a substituted or unsubstituted heteroaryl group, or a group of the formula: $—NR^4R^5$ (R^4 and R^5 are independently a hydrogen atom, a lower alkoxy-substituted or unsubstituted lower alkyl group, a cycloalkyl group, or an aralkyl group, or R^4 and R^5 may combine each other, and with the adjacent nitrogen atom to which they bond, form a saturated cyclic amino group having 4 to 8 carbon atoms as ones forming the said ring, and optionally having one $—NR^8—$ (R^8 is a hydrogen atom, a substituted or unsubstituted lower alkyl group, a substituted or unsubstituted phenyl group, a substituted or unsubstituted benzyl group, or a lower alkoxycarbonyl group) or one oxygen atom in the cycle thereof), provided that when Q is a substituted or unsubstituted heteroaryl group, then D^1 is not a direct bond, or

2)

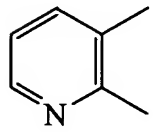
$—D^2—M—E—W$

wherein D^2 is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, M is an oxygen atom, a sulfur atom, a sulfinyl group or a sulfonyl group, or a group of the formula: —NHC(=O)—, —C(=O)NH— or $—NR^6—$ (R^6 is a hydrogen atom or a lower alkyl group), E is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, W is a hydroxy group, a carboxyl group, a substituted or unsubstituted heteroaryl group, or a group of the formula:

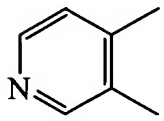
—NR^4R^5 (R^4 and R^5 are as defined above), provided that when W is a hydroxy group, a carboxyl group or a group of the formula: —NR^4R^5, then E is not a direct bond,

or a prodrug thereof, or a pharmaceutically acceptable salt of the same.

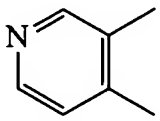
2. (Original) The agent for hyperlipidemia or arteriosclerosis according to claim 1, wherein in the formula (1), Ring A is one of the groups of the following formulae (a), (b) and (c):



(a)



(b)



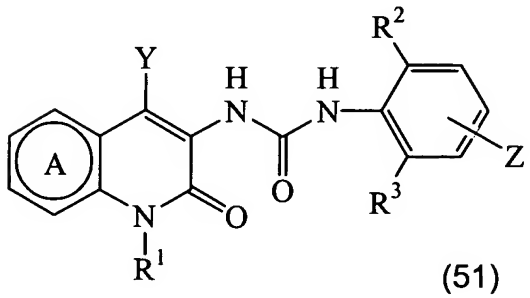
(c)

Y is a substituted or unsubstituted aromatic group;

R^1 is a substituted or unsubstituted alkyl group, or a substituted or unsubstituted alkenyl group;

Z is a group of the formula: —D^1—Q, wherein the D^1 is a direct bond, Q is a hydroxy group or a group of the formula: —NR^4R^5.

3. (Currently amended) The agent for hyperlipidemia or arteriosclerosis according to claim 1 ~~or 2~~, wherein the compound of formula (1) is represented by the formula (51):



(51)

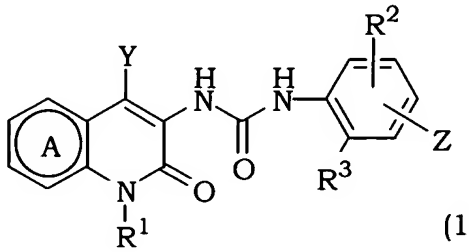
wherein the Ring A, R^1, R^2, R^3 and Z have the same meanings as defined in claim 1; Y is a phenyl group substituted by a group represented by the formula —M^1—E^1—T, wherein M^1 is an oxygen atom, E^1 is a hydrocarbon group having 2 to 4 carbon atoms, T is a hydroxy group or a

group represented by the formula —$NR^{41}R^{51}$ (R^{41} and R^{51} are independently a hydrogen atom, a lower alkoxy-substituted or unsubstituted lower alkyl group, a cycloalkyl group, a lower alkoxycarbonyl group, or an aralkyl group, or alternatively R^{41} and R^{51} may combine each other, and with the adjacent nitrogen atom to which they bond, form a saturated cyclic amino group having 4 to 8 carbon atoms as ones forming the said ring, and optionally having one —NR^{81}— (R^{81} is a hydrogen atom, a substituted or unsubstituted lower alkyl group, a substituted or unsubstituted phenyl group, a substituted or unsubstituted benzyl group, or a lower alkoxycarbonyl group) or one oxygen atom in the cycle thereof.

4. (Original) The agent for hyperlipidemia or arteriosclerosis according to claim 1, wherein the compound of formula (1) is N-[1-butyl-4-[3-[3-(hydroxy)propoxy]phenyl]-1,2-dihydro-2-oxo-1,8-naphthyridin-3-yl]-N'-(2,6-diisopropyl-4-aminophenyl)urea.

5. (Currently amended) The agent for hyperlipidemia or arteriosclerosis according to ~~any one of claims 1 to 4~~ claim 1, wherein 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor is selected from the group consisting of pravastatin, simvastatin, lovastatin, fluvastatin, atorvastatin, rosuvastatin, and pitavastatin.

6. (Original) An agent for hyperlipidemia or arteriosclerosis comprising a compound of the formula (1):



(1)

wherein Ring A is a substituted or unsubstituted pyridine ring;

Y is a substituted or unsubstituted alkyl group, a substituted or unsubstituted cycloalkyl group, or a substituted or unsubstituted aromatic group;

R^1 is a hydrogen atom, a substituted or unsubstituted alkyl group, a substituted or unsubstituted alkenyl group, a substituted or unsubstituted alkynyl group, or a substituted or unsubstituted cycloalkyl group;

R^2 is a hydrogen atom or a lower alkyl group;

R^3 is a lower alkyl group;

Z is a group represented by either of the following formula 1) or 2):

1)

$—D^1—Q$

wherein D^1 is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, Q is a hydroxy group, a carboxyl group, a substituted or unsubstituted heteroaryl group, or a group of the formula: $—NR^4R^5$ (R^4 and R^5 are independently a hydrogen atom, a lower alkoxy-substituted or unsubstituted lower alkyl group, a cycloalkyl group, or an aralkyl group, or R^4 and R^5 may combine each other, and with the adjacent nitrogen atom to which they bond, form a saturated cyclic amino group having 4 to 8 carbon atoms as ones forming the said ring, and optionally having one $—NR^8—$ (R^8 is a hydrogen atom, a substituted or unsubstituted lower alkyl group, a substituted or unsubstituted phenyl group, a substituted or unsubstituted benzyl group, or a lower alkoxycarbonyl group) or one oxygen atom in the cycle thereof), provided that when Q is a substituted or unsubstituted heteroaryl group, then D^1 is not a direct bond, or

2)

$—D^2—M—E—W$

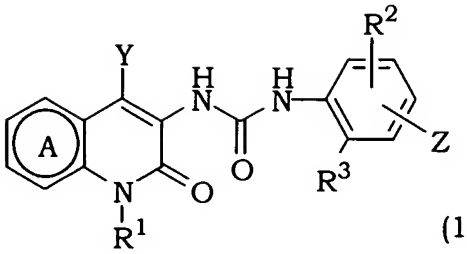
wherein D^2 is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, M is an oxygen atom, a sulfur atom, a sulfinyl group or a sulfonyl group, or a group of the formula: —NHC(=O)—, —C(=O)NH— or $—NR^6—$ (R^6 is a hydrogen atom or a lower alkyl group), E is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, W is a hydroxy group, a carboxyl group, a substituted or unsubstituted heteroaryl group, or a group of the formula: $—NR^4R^5$ (R^4 and R^5 are as defined above), provided that when W is a hydroxy group, a carboxyl group or a group of the formula: $—NR^4R^5$, then E is not a direct bond,

or a prodrug thereof or a pharmaceutically acceptable salt of the same,

to be used in combination with a pharmaceutical composition comprising 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor or a prodrug thereof or a pharmaceutically acceptable salt of the same and/or ezetimibe or a prodrug thereof or a pharmaceutically acceptable salt of the same.

7. (Original) A pharmaceutical composition for potentiating a blood cholesterol lowering action to be used in a therapy using a pharmaceutical composition comprising 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor or a prodrug thereof or a pharmaceutically acceptable salt of the same, and/or ezetimibe or a prodrug thereof or a pharmaceutically acceptable salt of the same,

which comprises a compound of the formula (1):



(1)

wherein Ring A is a substituted or unsubstituted pyridine ring;

Y is a substituted or unsubstituted alkyl group, a substituted or unsubstituted cycloalkyl group, or a substituted or unsubstituted aromatic group;

R^1 is a hydrogen atom, a substituted or unsubstituted alkyl group, a substituted or unsubstituted alkenyl group, a substituted or unsubstituted alkynyl group, or a substituted or unsubstituted cycloalkyl group;

R^2 is a hydrogen atom or a lower alkyl group;

R^3 is a lower alkyl group;

Z is a group represented by either of the following formula 1) or 2):

1)

$—D^1—Q$

wherein D^1 is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, Q is a hydroxy group, a carboxyl group, a substituted or unsubstituted heteroaryl group, or a group of the formula: $—NR^4R^5$ (R^4 and R^5 are independently a hydrogen atom, a lower alkoxy-substituted or unsubstituted lower alkyl group, a cycloalkyl group, or an aralkyl group, or R^4 and R^5 may combine each other, and with the adjacent nitrogen atom to which they bond, form a saturated cyclic amino group having 4 to 8 carbon atoms as

ones forming the said ring, and optionally having one —NR^8— (R^8 is a hydrogen atom, a substituted or unsubstituted lower alkyl group, a substituted or unsubstituted phenyl group, a substituted or unsubstituted benzyl group, or a lower alkoxycarbonyl group) or one oxygen atom in the cycle thereof), provided that when Q is a substituted or unsubstituted heteroaryl group, then D^1 is not a direct bond, or

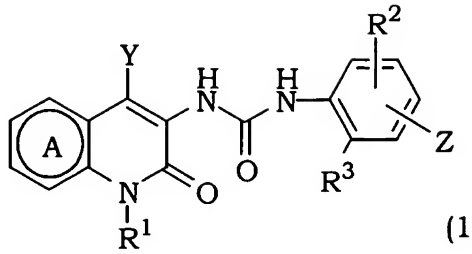
2)

—D^2—M—E—W

wherein D^2 is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, M is an oxygen atom, a sulfur atom, a sulfinyl group or a sulfonyl group, or a group of the formula: —NHC(=O) —, —C(=O)NH— or —NR^6— (R^6 is a hydrogen atom or a lower alkyl group), E is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, W is a hydroxy group, a carboxyl group, a substituted or unsubstituted heteroaryl group, or a group of the formula: —NR^4R^5 (R^4 and R^5 are as defined above), provided that when W is a hydroxy group, a carboxyl group or a group of the formula: —NR^4R^5, then E is not a direct bond,

or a prodrug thereof or a pharmaceutically acceptable salt of the same.

8. (Original) An agent for treating hyperlipidemia or arteriosclerosis comprising 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor or a prodrug thereof or a pharmaceutically acceptable salt of the same, and/or ezetimibe or a prodrug thereof or a pharmaceutically acceptable salt of the same, which is used in combination with a pharmaceutical composition comprising a compound of the formula (1):



(1)

wherein Ring A is a substituted or unsubstituted pyridine ring;

Y is a substituted or unsubstituted alkyl group, a substituted or unsubstituted cycloalkyl group, or a substituted or unsubstituted aromatic group;

R^1 is a hydrogen atom, a substituted or unsubstituted alkyl group, a substituted or unsubstituted alkenyl group, a substituted or unsubstituted alkynyl group, or a substituted or unsubstituted cycloalkyl group;

R^2 is a hydrogen atom or a lower alkyl group;

R^3 is a lower alkyl group;

Z is a group represented by either of the following formula 1) or 2):

1)

$—D^1—Q$

wherein D^1 is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, Q is a hydroxy group, a carboxyl group, a substituted or unsubstituted heteroaryl group, or a group of the formula: $—NR^4R^5$ (R^4 and R^5 are independently a hydrogen atom, a lower alkoxy-substituted or unsubstituted lower alkyl group, a cycloalkyl group, or an aralkyl group, or R^4 and R^5 may combine each other, and with the adjacent nitrogen atom to which they bond, form a saturated cyclic amino group having 4 to 8 carbon atoms as

ones forming the said ring, and optionally having one —NR^8—(R^8 is a hydrogen atom, a substituted or unsubstituted lower alkyl group, a substituted or unsubstituted phenyl group, a substituted or unsubstituted benzyl group, or a lower alkoxycarbonyl group) or one oxygen atom in the cycle thereof), provided that when Q is a substituted or unsubstituted heteroaryl group, then D^1 is not a direct bond, or

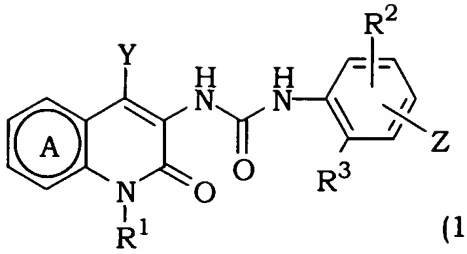
2)

—D^2—M—E—W

wherein D^2 is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, M is an oxygen atom, a sulfur atom, a sulfinyl group or a sulfonyl group, or a group of the formula: —NHC(=O)—, —C(=O)NH— or —NR^6— (R^6 is a hydrogen atom or a lower alkyl group), E is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, W is a hydroxy group, a carboxyl group, a substituted or unsubstituted heteroaryl group, or a group of the formula: —NR^4R^5 (R^4 and R^5 are as defined above), provided that when W is a hydroxy group, a carboxyl group or a group of the formula: —NR^4R^5, then E is not a direct bond,

or a prodrug thereof or a pharmaceutically acceptable salt of the same.

9. (Original) A pharmaceutical composition for potentiating a blood cholesterol lowering action comprising 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor or a prodrug thereof or a pharmaceutically acceptable salt of the same, and/or ezetimibe or a prodrug thereof or a pharmaceutically acceptable salt of the same, which is used in a therapy using a pharmaceutical composition comprising a compound of the formula (1):



(1)

wherein Ring A is a substituted or unsubstituted pyridine ring;

Y is a substituted or unsubstituted alkyl group, a substituted or unsubstituted cycloalkyl group, or a substituted or unsubstituted aromatic group;

R^1 is a hydrogen atom, a substituted or unsubstituted alkyl group, a substituted or unsubstituted alkenyl group, a substituted or unsubstituted alkynyl group, or a substituted or unsubstituted cycloalkyl group;

R^2 is a hydrogen atom or a lower alkyl group;

R^3 is a lower alkyl group;

Z is a group represented by either of the following formula 1) or 2):

1)

$—D^1—Q$

wherein D^1 is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, Q is a hydroxy group, a carboxyl group, a substituted or unsubstituted heteroaryl group, or a group of the formula: $—NR^4R^5$ (R^4 and R^5 are independently a hydrogen atom, a lower alkoxy-substituted or unsubstituted lower alkyl group, a cycloalkyl group, or an aralkyl group, or R^4 and R^5 may combine each other, and with the adjacent nitrogen atom to which they bond, form a saturated cyclic amino group having 4 to 8 carbon atoms as

ones forming the said ring, and optionally having one —NR^8— (R^8 is a hydrogen atom, a substituted or unsubstituted lower alkyl group, a substituted or unsubstituted phenyl group, a substituted or unsubstituted benzyl group, or a lower alkoxycarbonyl group) or one oxygen atom in the cycle thereof), provided that when Q is a substituted or unsubstituted heteroaryl group, then D^1 is not a direct bond, or

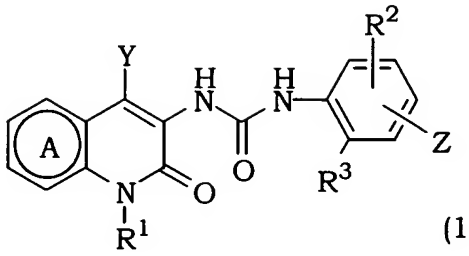
2)

—D^2—M—E—W

wherein D^2 is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, M is an oxygen atom, a sulfur atom, a sulfinyl group or a sulfonyl group, or a group of the formula: —NHC(=O)—, —C(=O)NH— or —NR^6— (R^6 is a hydrogen atom or a lower alkyl group), E is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, W is a hydroxy group, a carboxyl group, a substituted or unsubstituted heteroaryl group, or a group of the formula: —NR^4R^5 (R^4 and R^5 are as defined above), provided that when W is a hydroxy group, a carboxyl group or a group of the formula: —NR^4R^5, then E is not a direct bond,

or a prodrug thereof or a pharmaceutical acceptable salt of the same.

10. (Original) A commercial package which comprises a pharmaceutical composition comprising a compound of the formula (1):



(1)

wherein Ring A is a substituted or unsubstituted pyridine ring;

Y is a substituted or unsubstituted alkyl group, a substituted or unsubstituted cycloalkyl group, or a substituted or unsubstituted aromatic group;

R^1 is a hydrogen atom, a substituted or unsubstituted alkyl group, a substituted or unsubstituted alkenyl group, a substituted or unsubstituted alkynyl group, or a substituted or unsubstituted cycloalkyl group;

R^2 is a hydrogen atom or a lower alkyl group;

R^3 is a lower alkyl group;

Z is a group represented by either of the following formula 1) or 2):

1)

$—D^1—Q$

wherein D^1 is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, Q is a hydroxy group, a carboxyl group, a substituted or unsubstituted heteroaryl group, or a group of the formula: $—NR^4R^5$ (R^4 and R^5 are independently a hydrogen atom, a lower alkoxy-substituted or unsubstituted lower alkyl group, a cycloalkyl group, or an aralkyl group, or R^4 and R^5 may combine each other, and with the adjacent nitrogen atom to which they bond, form a saturated cyclic amino group having 4 to 8 carbon atoms as

ones forming the said ring, and optionally having one —NR^8— (R^8 is a hydrogen atom, a substituted or unsubstituted lower alkyl group, a substituted or unsubstituted phenyl group, a substituted or unsubstituted benzyl group, or a lower alkoxycarbonyl group) or one oxygen atom in the cycle thereof), provided that when Q is a substituted or unsubstituted heteroaryl group, then D^1 is not a direct bond, or

2)

—D^2—M—E—W

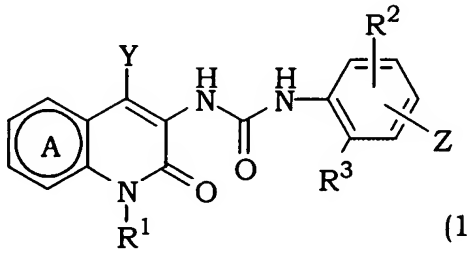
wherein D^2 is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, M is an oxygen atom, a sulfur atom, a sulfinyl group or a sulfonyl group, or a group of the formula: —NHC(=O)—, —C(=O)NH— or —NR^6— (R^6 is a hydrogen atom or a lower alkyl group), E is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, W is a hydroxy group, a carboxyl group, a substituted or unsubstituted heteroaryl group, or a group of the formula: —NR^4R^5 (R^4 and R^5 are as defined above), provided that when W is a hydroxy group, a carboxyl group or a group of the formula: —NR^4R^5, then E is not a direct bond,

or a prodrug thereof or a pharmaceutically acceptable salt of the same,

and a package insert indicating that said pharmaceutical composition may be used or should be used for potentiating a blood cholesterol lowering action with 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor or a prodrug thereof or a pharmaceutically acceptable salt of the same, and/or ezetimibe or a prodrug thereof or a pharmaceutically acceptable salt of the same.

11. (Original) A commercial package which comprises a pharmaceutical composition comprising 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor or a prodrug thereof or a pharmaceutically acceptable salt of the same, and/or ezetimibe or a prodrug thereof or a pharmaceutically acceptable salt of the same,

and a package insert indicating that said pharmaceutical composition may be used or should be used for potentiating a blood cholesterol lowering action with a compound of the formula (1):



(1)

wherein Ring A is a substituted or unsubstituted pyridine ring;

Y is a substituted or unsubstituted alkyl group, a substituted or unsubstituted cycloalkyl group, or a substituted or unsubstituted aromatic group;

R^1 is a hydrogen atom, a substituted or unsubstituted alkyl group, a substituted or unsubstituted alkenyl group, a substituted or unsubstituted alkynyl group, or a substituted or unsubstituted cycloalkyl group;

R^2 is a hydrogen atom or a lower alkyl group;

R^3 is a lower alkyl group;

Z is a group represented by either of the following formula 1) or 2):

1)

$—D^1—Q$

wherein D^1 is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, Q is a hydroxy group, a carboxyl group, a substituted or unsubstituted heteroaryl group, or a group of the formula: —NR^4R^5 (R^4 and R^5 are independently a hydrogen atom, a lower alkoxy-substituted or unsubstituted lower alkyl group, a cycloalkyl group, or an aralkyl group, or R^4 and R^5 may combine each other, and with the adjacent nitrogen atom to which they bond, form a saturated cyclic amino group having 4 to 8 carbon atoms as ones forming the said ring, and optionally having one —NR^8— (R^8 is a hydrogen atom, a substituted or unsubstituted lower alkyl group, a substituted or unsubstituted phenyl group, a substituted or unsubstituted benzyl group, or a lower alkoxycarbonyl group) or one oxygen atom in the cycle thereof), provided that when Q is a substituted or unsubstituted heteroaryl group, then D^1 is not a direct bond, or

2)

—D^2—M—E—W

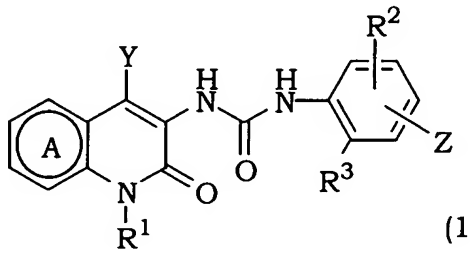
wherein D^2 is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, M is an oxygen atom, a sulfur atom, a sulfinyl group or a sulfonyl group, or a group of the formula: —NHC(=O)—, —C(=O)NH— or —NR^6— (R^6 is a hydrogen atom or a lower alkyl group), E is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, W is a hydroxy group, a carboxyl group, a substituted or unsubstituted heteroaryl group, or a group of the formula: —NR^4R^5 (R^4

and R^5 are as defined above), provided that when W is a hydroxy group, a carboxyl group or a group of the formula: $—NR^4R^5$, then E is not a direct bond,

or a prodrug thereof or a pharmaceutically acceptable salt of the same.

12. (Original) A commercial package which comprises a combination of

(A) a pharmaceutical composition comprising a compound of the formula (1):



(1)

wherein Ring A is a substituted or unsubstituted pyridine ring;

Y is a substituted or unsubstituted alkyl group, a substituted or unsubstituted cycloalkyl group, or a substituted or unsubstituted aromatic group;

R^1 is a hydrogen atom, a substituted or unsubstituted alkyl group, a substituted or unsubstituted alkenyl group, a substituted or unsubstituted alkynyl group, or a substituted or unsubstituted cycloalkyl group;

R^2 is a hydrogen atom or a lower alkyl group;

R^3 is a lower alkyl group;

Z is a group represented by either of the following formula 1) or 2):

1)

$—D^1—Q$

wherein D^1 is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, Q is a hydroxy group, a

carboxyl group, a substituted or unsubstituted heteroaryl group, or a group of the formula: —NR^4R^5 (R^4 and R^5 are independently a hydrogen atom, a lower alkoxy-substituted or unsubstituted lower alkyl group, a cycloalkyl group, or an aralkyl group, or R^4 and R^5 may combine each other, and with the adjacent nitrogen atom to which they bond, form a saturated cyclic amino group having 4 to 8 carbon atoms as ones forming the said ring, and optionally having one —NR^8— (R^8 is a hydrogen atom, a substituted or unsubstituted lower alkyl group, a substituted or unsubstituted phenyl group, a substituted or unsubstituted benzyl group, or a lower alkoxycarbonyl group) or one oxygen atom in the cycle thereof), provided that when Q is a substituted or unsubstituted heteroaryl group, then D^1 is not a direct bond, or

2)

—D^2—M—E—W

wherein D^2 is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, M is an oxygen atom, a sulfur atom, a sulfinyl group or a sulfonyl group, or a group of the formula: —NHC(=O)—, —C(=O)NH— or —NR^6— (R^6 is a hydrogen atom or a lower alkyl group), E is a direct bond or a divalent hydrocarbon group having 1 to 8 carbon atoms and optionally containing an unsaturated bond, W is a hydroxy group, a carboxyl group, a substituted or unsubstituted heteroaryl group, or a group of the formula: —NR^4R^5 (R^4 and R^5 are as defined above), provided that when W is a hydroxy group, a carboxyl group or a group of the formula: —NR^4R^5, then E is not a direct bond,

or a prodrug thereof or a pharmaceutically acceptable salt of the same; and

(B) 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitor or a prodrug thereof or a pharmaceutically acceptable salt of the same, and/or ezetimibe or a prodrug thereof or a pharmaceutically acceptable salt of the same;

and a package insert indicating that said combination may be used or should be used for lowering blood cholesterol.